

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231,

on

April 27, 1998

TOWNSEND and TOWNSEND and CREW LLP

By

Carmen H. Rhodes

Attorney Docket No. 12046A-010500US

PATENT

#6
5-13-98
Rhodes

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

HANS BOEHRINGER et al.

Application No.: 08/812,616

Filed: March 6, 1997

For: QUANTITATIVE LATERAL FLOW
ASSAYS AND DEVICES

Examiner: Chin, C

Art Unit: 1641

RESPONSE TO
RESTRICTION REQUIREMENT

MAY - 5 1998

MAIL ROOM CUSTOMER
SERVICE CENTER

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In response to the restriction requirement mailed March 31, 1998, please enter and consider the following remarks.

Restriction Requirement:

Claims 1-120 of this application have been subject to a restriction requirement under 35 U.S.C. §121 as set forth below:

I. Claims 1-15, drawn to a method of visually quantifying an amount of an analyte in a sample, classified in class 436, subclass 514;

II. Claims 16-23, drawn to a method of determining an amount of an analyte in a sample, classified in class 436, subclass 514;

III. Claims 24-34, drawn to a method of determining an amount of an analyte in a sample, classified in class 436, subclass 514;



IV. Claims 35-43, drawn to a method of determining an amount of an analyte in a sample, classified in class 436, subclass 514;

V. Claims 44-52, drawn to a method of determining an amount of an analyte in a sample, classified in class 436, subclass 514;

VI. Claims 53-71 and 120, drawn to a device and kit for determining an amount of an analyte in a sample, classified in class 422, subclass 56;

VII. Claims 72-81 and 120, drawn to a device and kit for determining an amount of an analyte in a sample, classified in class 422, subclass 56;

VIII. Claims 82-95 and 120, drawn to a device and kit for determining an amount of an analyte in a sample, classified in class 422, subclass 56;

IX. Claims 96-107 and 120, drawn to a device and kit for determining an amount of an analyte in a sample, classified in class 422, subclass 56; and

X. Claims 108-119 and 120, drawn to a device and kit for determining an amount of an analyte in a sample, classified in class 422, subclass 56.

In response, Applicants elect Group I (Claims 1-15) with traverse.

Restriction of an application is discretionary. A restriction requirement is made to avoid placing an undue examination burden on the Examiner and the Office. Where claims can be examined together without undue burden, the Examiner *must* examine the claims on the merits even though they are directed to independent and distinct inventions. See MPEP 803. In establishing that an "undue burden" would exist for co-examination of claims, the Examiner *must* show that examination of the claims would involve substantially different prior art searches, making the co-examination burdensome. To show undue burden resulting from searching difficulties, the Examiner *must* show one of the following, as set forth in the MPEP at § 808.02:

(1) *Separate classification thereof:*

This shows that each distinct subject has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search. Patents need not be cited to show separate classification.

(2) *A separate status in the art when they are classifiable together:*

Even though they are classified together, each subject can be shown to have formed a separate subject for inventive effort when an explanation indicates a recognition of separate inventive effort by inventors. Separate status in the art may be shown by citing patents which are evidence of such separate status, and also of a separate field of search.

(3) *A different field of search:*

Where it is necessary to search for one of the distinct subjects in places where no pertinent art to the other subject exists, a different field of search is shown, even though the two are classified together. The indicated different field of search must in fact be pertinent to the type of subject matter covered by the claims. Patents need not be cited to show different fields of search.

Where, however, the classification is the same and the field of search is the same and there is no clear indication of separate future classification and field of search, no reasons exist for dividing among related inventions.

See, The MPEP at §808.02, emphasis added.

In insisting upon restriction of the invention, the Examiner must establish that each of the groups has a separate status in the art, as evidenced, e.g., by separate classification, separate field of search, or citation of patents establishing separate status in the art. As the MPEP notes, "a mere statement of conclusion is inadequate. The reasons upon which the conclusion is based should be given." See, the MPEP at

§816. Despite the clear direction in the MPEP requiring clear reasoning to establish a reason for restriction and the logical reasons for such a requirement, Applicants respectfully note that the Examiner has not articulated the basis for the alleged undue examination burden.

Although Applicants appreciate the Examiner's rationale for the restriction groupings, Applicants respectively disagree and request that certain groups be recombined. For example, some of the groups are classified within the same Class 436 or 422 and combining those groups found within the same class would not create an undue search burden on the Examiner. In addition, the claims are allocated to one of two subclasses: 514 and 56, respectively.

In order to justify a restriction between claims, the inventions must be independent or distinct and be a serious burden on the Examiner if restriction is not required. Applicants do not find that the requirements for restriction practice have been properly met. However, in a spirit of cooperation, Applicants propose a regrouping of the claims such that Groups I, II, III and IV, directed to compositions and classified in Class 436, subclass 514, are combined. Further, Applicants request that Groups VI, VII, VIII and IX also be recombined, since they are all directed to methods of treatment and are located in Class 422, subclass 56. As a result, Applicants ask the Examiner to consider the following:

- A. Claims 1-43;
- B. Claims 44-52;
- C. Claims 53-107 and 120; and
- D. Claims 108-119 and 120.

Applicants hereby elect Group A for this alternative grouping of claims.

In view of the foregoing, Applicants believe all claims now pending in this application are in condition for review.

HANS BOEHRINGER et al.
Application No.: 08/812,616
Page 5

PATENT

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at (650) 326-2400 X5217.

Respectfully submitted,

Karen Babyak Dow

Karen B. Dow
Reg. No. 29,684

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, 8th Floor
San Francisco, California 94111-3834
(650) 326-2400 X5217
Fax (650) 326-2422
KBD:cmr

I:\KBD\WORK\12046A\105\105-REST.REQ